JUN 1 5 2001

K011040

Section II - Summary of Safety and Effectiveness

(1) Contact Information

Vincent Cutarelli
Sr. Vice President, Regulatory Affairs and Quality Assurance
Telephone: (949) 595-5424
FAX: (949) 595-4766
email: vcutarelli@endocare.com

(2) Company Information

Endocare, Inc.
7 Studebaker
Irvine, CA 92618
Telephone: (949) 595-4770
FAX: (949) 595-4766

(3) Device Name

Cryocare® Cardiac Surgical System

(4) Device Description

The Cryocare™ Cardiac Surgical System consists of a control unit that operates one to eight single-use, disposable CryoProbes. The control unit is software-controlled and operates off standard 110/230 VAC wall power. A 486 IBM-compatible microprocessor serves as the host computer and a screen displays the status of the system. System control is accomplished either directly through keys on the console itself (e.g., 1-probe system) or through a remote control keypad (e.g., 4 and 8-probe system). The CryoProbes operate on the Joule-Thompson principle and the refrigerative capacity is limited only to the distal tip of the probe. The CryoProbes incorporate a thermocouple to measure temperatures at the probe tip. The thermocouple is mounted inside each CryoProbe tip and its signal is used to monitor and control some operations of the system. The control unit can also control one to eight independent TempProbes™ to monitor temperatures in surrounding tissues. The temperature probes are standard T-type needle thermocouples.

The system utilizes inert argon gas as a cooling agent. The system is currently available in 1, 4 and 8-CryoProbe configurations. The performance characteristics and internal design of each model are equivalent. The primary differences are the number of valves to control the CryoProbes (e.g., 1-8), number of thermocouple inputs (e.g., 1-8) and the size of the outer case. No significant design changes have been made to the system as a result of this indication for use.

(5) Indications for Use

The Cryocare® Cardiac Surgical System is indicated for use in minimally invasive cardiac surgery procedures, including the surgical treatment of cardiac arrhythmias. The cardiac cryoprobes freeze the target tissue and block the electrical conduction pathway by creating an inflammatory response or cryonecrosis.

(6) Name of Predicate or Legally Marketed Device

Cryocare® Surgical System
CryoGen Cardiac Cryosurgical System

(7) Substantial Equivalence

The Cryocare® Cardiac Surgical System for the surgical treatment of cardiac arrhythmias is substantially equivalent to the Cryocare® Surgical System that was determined to be substantially equivalent on April 10, 1998 (reference K980110) and the CryoGen Cardiac Cryosurgery System that was determined to be substantially equivalent on February 3, 1998 (reference K974320).

(8) Technological Characteristics

The technological characteristics of the Cryocare® Cardiac Surgical System are the same as those of the predicate Cryocare® Surgical System and the CryoGen Cardiac Cryosurgery System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Vincent Cutarelli
Endocare, Inc.
7 Studebaker
Irvine, California 92618

Re: K011040
Trade Name: Cryocare® Cardiac Surgical System
Regulation Number: 878.4350
Regulatory Class: II (two)
Product Code: GEH
Dated: April 3, 2001
Received: April 5, 2001

Dear Mr. Cutarelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number: K011040

Device Name: Cryocare™ Cardiac Surgical System

Indications for Use: The Cryocare® Cardiac Surgical System is indicated for use in minimally invasive cardiac surgery procedures, including the surgical treatment of cardiac arrhythmias. The cardiac cryoprobes freeze the target tissue and block the electrical conduction pathway by creating an inflammatory response or cryonecrosis.

Concurrence of CDRH, Office of Device Evaluation (ODE):

Division of Cardiovascular & Respiratory Devices
510(k) Number K011040

Prescription Use: _X_
(Per 21 CFR 801.109)